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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,589	07/13/2001	Brian Paul Chadwick	28110/36120D	7125

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,589	CHADWICK ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 19-26 and 28-29 are pending and are being acted upon in this Office Action.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 19-26 and 28 and 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The transitional phrase "having" in claim 19 and 28 is indefinite and ambiguous. If the CD39L2 polypeptide is meant to be open ended. It is suggested that the term "comprising" be use. If said polypeptide is meant to be close, it is suggested the term "consisting of" be use.

Claim 20 as written is improper. It is suggested that the claim be recite: "The antibody or antigen binding fragment thereof of claim 19 wherein the antibody is a monoclonal antibody.

Claim 21 as written is improper. It is suggested that the claim be recite: "The antibody or antigen binding fragment thereof of claim 19 wherein the antigen binding fragment is an antigen binding fragment of a monoclonal antibody.

Claim 23 as written is improper. It is suggested that the claim be recite: "The antibody or antigen binding fragment thereof of claim 19 wherein the antibody is a polyclonal antibody.

Claim 24 as written is improper. It is suggested that the claim be recite: "The antibody or antigen binding fragment thereof of claim 19 wherein the antigen binding fragment is an antigen binding fragment of a polyclonal antibody.

The "detectable label" in claim 25 lacks antecedent basis in base claim 19. It is suggested that the claim be recite: "A labeled antibody or antigen binding fragment thereof wherein the antibody or antigen binding fragment thereof of Claim 19 is labeled with a detectable label".

Claim 26 as written is improper. It is suggested that the claim be recite: "The labeled antibody or antigen binding fragment thereof of claim 25 wherein the detectable label is .....or paramagnetic moiety".

The "reagent capable of detecting the presence of a bound antibody" in claim 29 is ambiguous and indefinite because it is clear if the bound antibody is the same antibody that binds to the polypeptide comprising SEQ ID NO: 2 since the article "a" is used.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 19-26 and 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,476,211B1 (Nov 2002, PTO 892).

The '211 patent teaches an isolated antibody such as monoclonal and polyclonal antibody and binding fragment thereof that bind specifically to CD39L2 polypeptide having the amino acid sequence 100% identical to the claimed SEQ ID NO: 2 (See column 63, lines 1-9, column 20 bridging column 20, lines 1-65 and column 21, lines 1-3, in particular). The '211 patent further teaches the reference antibody is labeled with a detectable label such as radioisotope, affinity label such as biotin, enzymatic label such as horseradish peroxidase, fluorescent label such as FITC or paramagnetic atoms (See column 20, lines 55-5, in particular). The '211 patent further teaches a method of making hybridoma that produces the reference monoclonal antibody (See column 20, line 40-45, in particular). The '211 patent also teach a kit comprising the reference antibody and polypeptide or immunologically reactive fragment thereof with a wash agent or agent capable of detecting the bound antibody for diagnostic assays (See column 24, lines 35-56, in particular). Thus, the reference teachings anticipate the claimed invention.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al* (Biochim Biophys Acta 1386(1): 65-78, July 1998, PTO 892) in view of Harlow *et al* (in Antibodies a Laboratory Manual, 1988, Cold Spring harbor laboratory publication, Cold Spring Harbor, NY, pages 92-94, pages 116-117, pages 626-629) or Campbell *et al* (in Monoclonal Antibody Technology, 1984, Elsevier Science Publisher, New York, NY, page 1-32; PTO 892).

Smith *et al* teach a polypeptide that has a long stretch of amino acid residues identical to the claimed polypeptide having the amino acid sequence of SEQ ID NO: 2 (See Figure 5, ACR1, ACR2, ACR3 and ACR4, in particular). Smith *et al* teach that the reference polypeptide has conserved four apyrase ACR regions that related to both ecto-ATPase and other CD39 ecto-apyrases (See abstract, page 71, column 2, in particular).

The claimed invention in claim 19 differs from the teachings of the reference only that an isolated antibody or fragment thereof which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2.

The claimed invention in claim 20 differs from the teachings of the reference only that an isolated antibody or fragment thereof which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 wherein the antibody is monoclonal.

The claimed invention in claim 21 differs from the teachings of the reference only that the antibody fragment is a fragment of the monoclonal antibody which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2.

The claimed invention in claim 22 differs from the teachings of the reference only that a hybridoma which produces the monoclonal antibody which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2.

The claimed invention in claim 23 differs from the teachings of the reference only the antibody that specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 is a polyclonal antibody.

The claimed invention in claim 24 differs from the teachings of the reference only that the antigen binding fragment is an antigen binding fragment of a polyclonal antibody which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2.

The claimed invention in claim 25 differs from the teachings of the references only that the antibody or fragment thereof which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 comprises a detectable label.

The claimed invention in claim 26 differs from the teachings of the reference only that the antibody or fragment thereof which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 wherein the antibody comprises a detectable label wherein the label is radioisotope, affinity label, enzymatic label, or fluorescent label.

Harlow *et al* teach a method of producing polyclonal or monoclonal antibody (See page 92-94, page 116-117 in particular) as well as antibodies fragment to any antigen of interested for detection assays (See page 626-629, in particular). Harlow *et al* teach that the problems of using multivalent antibodies on mammalian cells often will lead to capping and internalization of the antigen which can be overcome by using fragments of antibodies (See page 626 in particular). Harlow *et al* teach a method of making monoclonal antibody such as hybridoma or cell line that produces antibody that binds specifically to any antigen (See page 145-149, in particular). Harlow *et al* also teach a method of labeling any antibody with various labels such as enzyme, fluorescent, radioisotope (See chapter 9, in particular) for various detection assays. The advantages of enzyme labeling are longer shelf life, and higher sensitivity (See page 322, in particular). Harlow *et al* teach that the advantages of monoclonal antibody are their binding specificity, their homogeneity and their ability to be produced in unlimited quantities by hybridoma (See page 141, last full paragraph, in particular).

Campbell *et al* teach that "it is customary now for any group working on a macromolecule to both clone the gene encoding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" for further basic research and diagnostic uses (See page17, and 29, section Basic Research, in particular). Campbell *et al* further teach conventional antiserum which is polyclonal antibody (See page 4, comparison of monoclonal antibodies and conventional antiserum, in particular).

Therefore, it would be been obvious to one having ordinary skill in the art at the time the invention was made to produce monoclonal or polyclonal antibody and binding fragment thereof as taught by Harlow *et al* or Campbell *et al* that binds specifically to the polypeptide as taught by Smith *et al* for detection assay as well as for further characterization as taught by Harlow *et al* and Campbell *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to make monoclonal or polyclonal antibodies to the claimed polypeptide based on the fact that it is a conventional practice in the art to do so for further study such as basic research, characterization and identification of a polypeptide as taught by Campbell *et al.* One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to make monoclonal antibody because Harlow *et al* teach that the advantage of monoclonal antibody are their binding specificity, their homogeneity and their ability to be produced in unlimited quantities (See page 141, last full paragraph, in particular). One having ordinary skill in the art would have been motivated to make antibody fragment because Harlow *et al* teach that antibody fragments such as Fab can overcome the problem of capping and internalization of the antigen on mammalian cell when using multivalent antibodies (See page 626 in particular). Harlow *et al* teach that the advantages of enzyme labeling are longer shelf life, and higher sensitivity (See page 322, in particular). Smith *et al* teach that the reference polypeptide has conserved four apyrase ACR regions that related to both ecto-ATPase and other CD39 ecto-apyrases (See abstract, page 71, column 2, in particular). Given the reference polypeptide has a long stretch of identical amino acids to the claimed polypeptide of SEQ ID NO: 2, the antibody such as monoclonal and polyclonal antibody and binding fragment thereof made from the reference polypeptide appears to bind to the claimed polypeptide. Since the Patent Office does not have the facilities for

examining and comparing the antibodies of the instant invention to those of the prior art, the burden is on applicant to show that the prior art antibody is different from the claimed antibody. See In re Best, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

9. Claim 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al* (Biochim Biophys Acta 1386(1): 65-78, July 1998, PTO 892) in view of Harlow *et al* (in Antibodies a Laboratory Manual, 1988, Cold Spring harbor laboratory publication, Cold Spring Harbor, NY, pages 92-94, pages 116-117, pages 626-629) or Campbell *et al* (in Monoclonal Antibody Technology, 1984, Elsevier Science Publisher, New York, NY, page 1-32; PTO 892) as applied to claims 19-26 above and further in view of U.S. Pat No. 5,858,682 (filed Aug 1996, PTO 892; see entire document).

The combined teachings of Smith *et al,* and Harlow *et al* and Campbell *et al* have been discussed supra.

The claimed invention in claim 28 differs from the combined teaching of the references only that a kit comprising the antibody or antibody fragment which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 and an immunologically reactive fragment of SEQ ID NO: 2.

The claimed invention in claim 29 differs from the combined teaching of the references only that a kit comprising the antibody or antibody fragment which specifically binds to CD39L2 polypeptide having the amino acid sequence of SEQ ID NO: 2 and a wash reagent or a reagent capable of detecting the presence of a bound antibody.

The '682 patent teaches a kit comprising an antibody for diagnostic assays (See column 3, line 40; column 6, line 17; column 8, line 36, in particular). The '682 patent further teaches an antibody which is associated with a solid phase (see column 9, line 23, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody in the kit as taught by the '682 patent for the antibody taught by Smith and Harlow and Campell et al that binds specifically to the reference polypeptide as taught by Smith *et al* for diagnostic assays or further characterization.

One would have been motivated, with a reasonable expectation of success to do this for convenience and commercial expedience. A kit will allow for ease of use for the practitioner since all the necessary reagents, standard such as the reference polypeptide or fragment to which the antibody binds and instructions for use are included in a kit as taught by '682 (See column 8,

line 36-57, in particular). From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidence by the references.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist (customer service) whose telephone number is (703) 872-9305.

12. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401. The IFW official Fax number is (703) 872-9306. For After Final, the Fax number is (703) 872-9307.

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